

WE CLAIM:

1. A DNA vaccine suitable for eliciting an immune response against cancer cells comprising a DNA construct operably encoding at least one cancer-associated Inhibitor of Apoptosis-family protein (IAP-family protein) and at least one immunoactive gene product in a pharmaceutically acceptable carrier.
2. The DNA vaccine of claim 1 wherein the cancer-associated IAP-family protein is selected from the group consisting of a survivin protein and a livin protein.
3. The DNA vaccine of claim 1 wherein the DNA operably encodes a survivin protein selected from the group consisting of (a) wild-type human survivin having the amino acid residue sequence of SEQ ID NO: 2, (b) an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 2, (c) a splice variant of human survivin having the amino acid residue sequence of SEQ ID NO: 23, (d) a splice variant of human survivin having the amino acid residue sequence of SEQ ID NO: 24, and (e) a fragment of a survivin protein that binds to a MHC class I molecule and is recognized by cytotoxic T cells.
4. The DNA vaccine of claim 1 wherein the DNA construct operably encodes wild-type human survivin having the an amino acid residue sequence of SEQ ID NO: 2.
5. The DNA vaccine of claim 1 wherein the DNA construct operably encodes human survivin splice variant having the an amino acid residue sequence of SEQ ID NO: 23.
6. The DNA vaccine of claim 1 wherein the DNA construct operably encodes human survivin splice variant having the an amino acid residue sequence of SEQ ID NO: 24.
7. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 2.

8. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 90% identical to SEQ ID NO: 2.

5 9. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 95% identical to SEQ ID NO: 2.

10 10. The DNA vaccine of claim 1 wherein the DNA construct operably encodes a livin protein selected from the group consisting of (a) full length wild-type human livin alpha splice variant having the amino acid residue sequence of SEQ ID NO: 27, (b) human livin beta splice variant having the amino acid residue sequence of SEQ ID NO: 29, (c) an immunogenic homolog of full length wild-type human livin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 27, (d) an immunogenic homolog of wild-type human livin beta splice variant having an amino acid residue sequence at least 80% identical to SEQ ID NO: 29, and
15 (e) a fragment of a livin protein that binds to a MHC class I molecule and is recognized by cytotoxic T cells.

11. The DNA vaccine of claim 1 wherein the DNA construct operably encodes human livin splice variant having the an amino acid residue sequence of SEQ ID NO: 27.

20 12. The DNA vaccine of claim 1 wherein the DNA construct operably encodes human livin splice variant having the an amino acid residue sequence of SEQ ID NO: 29.

13. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human survivin having an amino acid residue sequence at least 80% identical to SEQ ID NO: 27 or SEQ ID NO: 29.
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14. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human livin having an

amino acid residue sequence at least 90% identical to SEQ ID NO: 27 or SEQ ID NO: 29.

5 15. The DNA vaccine of claim 1 wherein the DNA construct operably encodes an immunogenic homolog of wild-type human livin having an amino acid residue sequence at least 95% identical to SEQ ID NO: 27 or SEQ ID NO: 29.

 16. The DNA vaccine of claim 1 wherein the immunoactive gene product operably encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

10 17. The DNA vaccine of claim 16 wherein the cytokine is selected from the group consisting of a chemokine, a hematopoietin, an interferon, a natural killer cell stimulatory factor, and a cytokine production-inducing factor.

 18. The DNA vaccine of claim 17 wherein the cytokine is human CCL21.

15 19. The DNA vaccine of claim 16 wherein the ligand for a natural killer cell surface receptor operably encoded by the DNA construct is a stress-inducible protein selected from the group consisting of human MICA, human MICB, human ULBP1, human ULBP2, and human ULBP3.

20 20. The DNA vaccine of claim 1 wherein the DNA construct is operably incorporated in a plasmid vector.

 21. The DNA vaccine of claim 1 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.

25 22. The DNA vaccine of claim 21 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG*, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.

 23. The DNA vaccine of claim 21 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.

24. The DNA vaccine of claim 23 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻ strain of *Salmonella typhimurium*.

25. The DNA vaccine of claim 23 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻, *dam*⁻ strain of *Salmonella typhimurium*.

5 26. The DNA vaccine of claim 1 wherein the DNA construct operably encoding the cancer-associated IAP-family protein comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 26 and SEQ ID NO: 28.

10 27. The DNA vaccine of claim 26 wherein the DNA construct is operably incorporated in an attenuated *Salmonella typhimurium* vector.

28. The DNA vaccine of claim 1 wherein the DNA construct operably encoding the immunoreactive gene product comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, and
15 SEQ ID NO: 21.

29. The DNA vaccine of claim 28 wherein the DNA construct is operably incorporated in an attenuated *Salmonella typhimurium* vector.

30. A method of inhibiting tumor growth in a mammal comprising the step of administering to the mammal an effective immunological
20 response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor cells.

31. The method of claim 30 wherein the cancer-associated IAP-family protein encoded by the DNA construct is selected from the group consisting of a survivin protein and a livin protein.
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32. The method of claim 30 wherein the immunoactive gene product encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

33. The method of claim 30 wherein the mammal is a human.
34. The method of claim 30 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.
- 5 35. The method of claim 34 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, BCG, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.
36. The method of claim 34 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.
- 10 37. The method of claim 36 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻ strain of *Salmonella typhimurium*.
38. The DNA vaccine of claim 36 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻, *dam*⁻ strain of *Salmonella typhimurium*.
- 15 39. An article of manufacture comprising a vaccine of claim 1 packaged in a hermetically sealed, sterile container, the container having a label affixed thereto, the label bearing printed material identifying the vaccine and providing information useful to an individual administering the vaccine to a patient.
- 20 40. An isolated plasmid vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product.
41. A transformed host cell transfected with a vector comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product.
- 25 42. A method of vaccinating a mammal against cancer, the method comprising the step of administering to the mammal an effective immunological response eliciting amount of a DNA vaccine comprising a DNA construct operably encoding a cancer-associated IAP-family protein and an immunoactive gene product in a pharmaceutically acceptable carrier, whereby said mammal exhibits an immune response elicited by vaccine and specific to tumor

cells.

43. The method of claim 42 wherein the cancer-associated IAP-family protein encoded by the DNA construct is selected from the group consisting of a survivin protein and a livin protein.

5 44. The method of claim 42 wherein the immunoactive gene product encoded by the DNA construct is a cytokine or a ligand for a natural killer cell surface receptor.

45. The method of claim 42 wherein the mammal is a human.

10 46. The method of claim 42 wherein the DNA construct is operably incorporated in an attenuated bacterial vector.

47. The method of claim 46 wherein the attenuated bacterial vector is selected from the group consisting of attenuated *Salmonella typhimurium*, *Salmonella typhi*, *Shigella* species, *Bacillus* species, *Lactobacillus* species, *BCG*, *Escherichia coli*, *Vibrio cholerae*, *Campylobacter* species, and *Listeria* species.

15 48. The method of claim 46 wherein the attenuated bacterial vector is an attenuated *Salmonella typhimurium*.

49. The method of claim 48 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻ strain of *Salmonella typhimurium*.

20 50. The DNA vaccine of claim 49 wherein the attenuated *Salmonella typhimurium* is an *AroA*⁻, *dam*⁻ strain of *Salmonella typhimurium*.